

Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 3: Assessment of economic outcome

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A comprehensive economic analysis generally involves the calculation of indirect and direct health costs from a societal perspective as opposed to simply reporting costs from a hospital or payer perspective. Hospital charges for a surgical procedure must be converted to cost data when performing a cost-effectiveness analysis. Once cost data has been calculated, quality-adjusted life year data from a surgical treatment are calculated by using a preference-based health-related quality-of-life instrument such as the EQ-5D. A recent cost-utility analysis from a single study has demonstrated the long-term (over an 8-year time period) benefits of circumferential fusions over stand-alone posterolateral fusions. In addition, economic analysis from a single study has found that lumbar fusion for selected patients with low-back pain can be recommended from an economic perspective. Recent economic analysis, from a single study, finds that femoral ring allograft might be more cost-effective compared with a specific titanium cage when performing an anterior lumbar interbody fusion plus posterolateral fusion.
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KEY WORDS • fusion • lumbar spine • cost-effectiveness • outcomes • practice guidelines

Recommendations

There is no evidence that conflicts with the previous recommendations published in the original version of the

Abbreviations used in this paper: ALIF = anterior lumbar interbody fusion; CCR = cost-to-charge ratio; CMS = Center for Medicare and Medicaid Services; CPT = Current Procedural Terminology; DRG = Diagnosis-Related Group; FRA = femoral ring allograft; HR-QOL = health-related quality of life; ICBG = iliac crest bone graft; ICD = International Classification of Diseases; ICER = incremental cost-effectiveness ratio; LOS = length of hospital stay; MIS = minimally invasive surgery; ODI = Oswestry Disability Index; QALY = quality-adjusted life year; rhBMP-2 = recombinant human bone morphogenetic protein-2; SEK = Swedish kronor; SF-36 = 36-Item Short Form Health Survey; SPORT = Spine Patient Outcomes Research Trial; TC = titanium cage; TDR = total lumbar disc replacement; TLIF = transforaminal lumbar interbody fusion; UK = United Kingdom; VAS = visual analog scale.

“Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine.”

Grade B

There is Level I evidence (single study) to recommend the use of a circumferential fusion (ALIF + posterolateral fusion) as a more cost-effective option (over an 8-year time period) than stand-alone posterolateral fusion.

There is Level I evidence (single study) to recommend either total lumbar disc replacement (TDR) or lumbar fusion from an economic perspective for the treatment of selected patients with chronic low back pain (over a 2-year time period).

Grade C

With respect to the combination of anterior lumbar interbody fusion (ALIF) plus posterolateral fusion, there

Part 3: Assessment of economic outcome

is Level II evidence that the use of a femoral ring allograft for interbody fusion is a more cost-effective interbody option than the use of a specific titanium cage.

From an economic perspective, both iliac crest bone graft and recombinant human bone morphogenetic protein-2 (rhBMP-2) are posterolateral fusion graft options in patients over the age of 60 (Level IV evidence).

From an economic perspective, both minimally invasive and open transforaminal lumbar interbody fusion (TLIF) techniques are options when treating patients with symptomatic Grade I degenerative spondylolisthesis (Level IV evidence).

Grade I

There are conflicting data regarding the cost-effectiveness of cell-salvage auto-transfusion as an adjunct to lumbar fusion (Level IV evidence).

Rationale

Ongoing changes in national health care policy have created an increased awareness on medical resource allocation and greater emphasis on cost-benefit analyses. As part of the American Recovery and Reinvestment Act of 2009, the federal government has allocated \$1.1 billion in funds toward comparative-effectiveness research.^{9,23} An area of specific interest has been the application of lumbar fusion in the management of degenerative spine disease, with a focus on establishing clinical efficacy and cost-effectiveness.³¹ Management of chronic degenerative spinal conditions in the United States is estimated to cost nearly \$85 billion annually, with a significant percentage attributed to the dramatic increase in the frequency of lumbar fusion procedures.^{13,15,25} In 2004, more than 300,000 spinal fusions were performed in the US, accounting for more than \$16 billion in hospital charges alone.¹⁴ Advances in surgical fusion technologies have improved the surgeon's ability to attain a solid arthrodesis and expand the treatment options available for patients with spine disorders. Since the initial publication of the Lumbar Fusion Guidelines, there is recognition that the evolution of devices and techniques for lumbar fusion impacts not only surgical outcomes but also health care costs. The purpose of this qualitative review is to evaluate current research that examines the economic impact of lumbar fusion on the management of degenerative lumbar spine disease. The expense of fusion surgery and new fusion technologies must be weighed against the incremental improvement in patient outcomes and quality of life.

Search Criteria

A search of the National Library of Medicine database of literature was performed with limits: (("2002" [PDAT]: "2011"[PDAT]) AND English[lang]). Using the following terms: ("lumbar" AND "fusion"[All Fields]) yielded 4002 citations. The following terms were combined: ("lumbar" AND "fusion" AND "outcomes"[All Fields]), which yielded 807 citations and ("lumbar" AND "fusion" AND "cost"[All Fields]) which yielded 154 cita-

tions. The titles and abstracts of the 154 articles were reviewed. In addition, additional searches were performed with terms: (("lumbar fusion"[MeSH]) AND ("cost effectiveness"[MeSH]) OR ("employment status"[MeSH]), ("mortality") OR ("medical care costs[MeSH])" OR ("cost containment"[MeSH] OR "cost comparison"[MeSH]) OR ("spondylolisthesis")). Of the articles reviewed, 13 clinical series focusing on adult patients who underwent lumbar fusion procedures were selected based on the inclusion of an economic analysis.

A comprehensive economic analysis from a societal perspective that included multivariate sensitivity analyses was performed in 4 articles.^{16,18,36,39} A cost analysis investigating various surgical approaches for lumbar fusion was performed in 1 study.³⁶ Another study performed a cost analysis on the type of interbody device used in lumbar fusion.¹⁶ Two randomized trials compared outcomes and cost of lumbar fusion to conservative management.^{19,39} Two studies examined the comparative cost-effectiveness of minimally invasive versus open TLIF.^{43,44} One preliminary study provided cost-effectiveness data for TLIF procedures.¹ Six studies addressed incremental cost-effectiveness of new technology for lumbar fusion.^{2,7,8,20,30,34}

Scientific Foundation

A cost-utility analysis is a specific type of cost-effectiveness evaluation that allows a comparison of 2 alternative treatment strategies in terms of the cost required for a given clinical outcome. These analyses are measured in terms of quality-adjusted life years (QALYs) gained, taking into account both the quantity and quality of life resulting from a given intervention.^{21,32} For calculation of QALYs, patients must be surveyed using a preference-based health-related quality-of-life (HR-QOL) outcome instrument, such as the EQ-5D (EuroQol Group).^{29,37} Another commonly used preference-based HR-QOL instrument is the SF-6D,⁴ which consists of 11 items selected from the 36-Item Short Form Health Survey (SF-36).⁵ An HR-QOL score is converted to a "health utility," typically a number on a continuum between 0, indicating death, and 1, indicating perfect health. Negative values can be generated when conditions considered worse than death exist.³⁸ A QALY is determined by the number of years in a given health state multiplied by the utility score assigned to that particular health state. A single year spent in perfect health is given the value of 1 QALY.

When comparing 2 treatment strategies, A and B, it is necessary to know the incremental cost-utility ratio (similar to the incremental cost-effectiveness ratio [ICER]). The ICER of Treatment B versus A is calculated as: (Cost of B – Cost of A)/(QALYs gained from B – QALYs gained from A).

From this calculation, the incremental cost of each additional QALY is determined when Treatment B is chosen over Treatment A. The acceptable cost per additional QALY represents society's willingness to pay and serves as a foundation for cost-effectiveness analyses. Since 1982, \$50,000 per QALY gained has been cited as the threshold for a cost-effective intervention,⁴² although

more recent proposals argue for a cut-off value closer to \$100,000 or more, reflecting inflation and increased costs for research and development.³

There are 3 main categories of cost: direct, indirect, and intangible. Direct costs are resources that are consumed by the surgical procedure (i.e., operating room supplies, surgeon time and labor, cost of hospital stay). Indirect costs generally refer to a loss of productivity due to the morbidity or mortality of the surgical procedure. For example, the amount of work missed by the patient and/or their caretaker during the recovery period would qualify as indirect costs. Intangible costs include the pain and suffering from the surgical procedure. Both the indirect and the intangible costs are often difficult to quantify in monetary terms. Therefore, the total cost of a surgical procedure is based on the quantity of resources used and the assignment of cost to these resources. Determining the quantity of resources used is relatively straightforward for a surgical procedure. However, unit costs may vary between different countries, geographic regions, time periods, or hospitals. The cost perspective ("costs to whom") must be considered and expressly stated in any economic analysis. Costs to the patient for an intervention may be quite different from those to a hospital, a third-party payer, or to society itself.

Several methods have been introduced to estimate the total cost of a surgical procedure. One method utilizes the total hospital charge for the procedure and admission. The hospital charge is based on several data coding systems that are currently used to determine reimbursement, including the diagnosis-related group (DRG), International Classification of Diseases (ICD) system, and current procedural terminology (CPT) system.^{10,12,33,45} This method, however, fails to reflect the actual amount of reimbursement received by the hospital or physician, or the actual costs, counting instead upon charges as a surrogate for costs. For the hospital charges of different centers to be used as a proxy for direct costs, a cost-to-charge ratio (CCR) must be calculated and applied. The CCR is specific for every hospital, for many departments within the hospital, and for a given time period. The CCR is calculated from Medicare Hospital Cost Reports (Worksheet C or D) in combination with claims data. Although obtaining CCRs is labor intensive, it has been suggested that this approach is the most accurate way to determine actual "cost" when comparing different centers.¹⁷ Other methods for calculating cost of a surgical procedure include using total Medicare charges allowed, or the Medicare reimbursement. The most common and simplest way to estimate the direct cost for a procedure is using Medicare payments.^{35,41} Real hospital costs can also be estimated by using the Center for Medicare and Medicaid Services (CMS) reimbursement value for DRG and CPT codes.

Micro-costing methodology involves measuring all the costs and benefits of a treatment as accurately as possible. It becomes particularly useful when evaluating and comparing regional differences in the resource utilization for a particular surgical procedure. However, micro-costing analysis is expensive and time-consuming due to extensive record keeping and database management. Of-

ten details, specific to a single institution, limit the generalizability of the conclusions. Finally, there are some elements of the micro-costing analysis that inevitably require estimation, which will also compromise the validity of the conclusions.²⁸

An understanding of the methodology used to determine cost is critical when interpreting the results and conclusions of a study.¹¹ For example, in the recent Spine Patient Outcomes Research Trial (SPORT), the cost-effectiveness of surgery relative to nonoperative treatment for lumbar disc disease was \$69,403/QALY using overall adult surgery costs (all payers), but only \$34,355/QALY using Medicare population-specific surgery costs.⁴⁰ Using Medicare-based reimbursements will significantly lower the estimate of medical costs for any given treatment, which may be appropriate in older aged individuals, but irrelevant when considering younger patients with better (e.g., Workers Compensation) or worse (e.g., Medicaid) reimbursements.

Literature Review

Comparison of Lumbar Fusion to Nonoperative Therapy

Utilizing 2-year follow-up data from the SPORT study, Tosteson et al. investigated the cost-effectiveness of lumbar fusion for patients with degenerative spondylolisthesis and spinal stenosis.³⁹ Patients underwent nonoperative treatment, decompressive laminectomy, or laminectomy with fusion, with or without instrumentation and/or iliac crest bone graft. QALYs were calculated from EQ-5D scores at baseline, 6 weeks, and 3, 6, 12, and 24 months following treatment. Direct and indirect costs were collected prospectively based on 2004 Medicare payments. Operative management of spinal stenosis improved health significantly compared with nonoperative care, 0.17 QALYs gained, at a cost of \$77,600 per QALY. Operative management of degenerative spondylolisthesis, 93% of which were lumbar fusions, provided significant benefit, with 0.23 QALYs gained at a cost of \$115,600 per QALY. Although \$115,600 is greater than the accepted societal expense per QALY, it is much less than previous estimates. Kuntz et al. reported that an instrumented lumbar fusion procedure cost \$3,112,800 per QALY and instead favored noninstrumented fusion with a comparative medical benefit.²⁴ Although Tosteson et al. performed a rigorous cost analysis, the underlying heterogeneity of the study population and surgical techniques limits the validity of the study conclusions. In addition, follow-up data beyond 2 years will be essential to order to formulate meaningful recommendations regarding the cost-effectiveness of lumbar fusion over nonfusion treatments for lumbar degenerative disorders. This study provides Level II evidence that surgery for degenerative spondylolisthesis is effective but more costly than surgery for spinal stenosis (see Table 1).

Fritzell et al. performed a randomized controlled trial of patients with chronic low-back pain who underwent either lumbar fusion or nonoperative treatment.¹⁹ Two hundred eighty-four patients from multiple centers were randomized, and outcomes were measured by the

Part 3: Assessment of economic outcome

TABLE 1: Economic outcome: summary of evidence*

Authors & Year	Level of Evidence	Description of Study	Conclusions
Soegaard et al., 2007	I	146 pts randomized to either PLF or circumferential fusion w/ long-term (4–8 yrs) EQ-5D utility outcomes assessment. Follow-up was 86%. Multi-way sensitivity analyses were performed. Circumferential lumbar fusion demonstrated clinical superiority over PLF. For each QALY gained by circumferential fusion, there was an incremental saving of \$49,306.	Circumferential fusion was dominant over PLF; it is cost-effective.
Fritzell et al., 2011	I	152 pts w/ chronic LBP randomized to total disc replacement (TDR) or lumbar fusion. EQ-5D scores & costs were assessed at 2 yrs. Follow-up was 99%. Appropriate sensitivity analyses were performed. Outcomes & cost-effectiveness profiles were comparable.	Cost-effectiveness of TDR & lumbar fusion are comparable for chronic LBP.
Freeman et al., 2007	II	83 pts undergoing circumferential lumbar fusion, randomized to receive either titanium cages (TC) or femoral ring allograft (FRA). SF-6D used for cost-utility assessment. Follow-up was 94%. Multi-way sensitivity analyses were performed. At 2 yrs, mean QALY gain per pt was significantly greater for FRA (0.1914) than TC (0.0522). FRA was £1950 less expensive than TC.	The study was downgraded to Level II evidence because the study population was heterogeneous. FRA was dominant over a specific TC that was studied. FRA was cheaper & generated greater QALY gains.
Fritzell et al., 2004	III	284 pts w/ chronic LBP randomized to lumbar fusion or nonoperative treatment. Outcomes & costs were assessed at 2 yrs. 97% follow-up. Appropriate sensitivity analyses. QALYs gained were not calculated. Incremental cost of surgery for unit effect gained was SEK 2600 for global improvement; SEK 5200 for back pain by VAS; SEK 11,300 for ODI; SEK 4100 for return to work.	Outcomes were improved w/ fusion surgery compared to nonoperative treatment. Fusion surgery was more expensive than nonoperative treatment.
Savidou et al., 2009	IV	50 pts undergoing PLF randomized to receive cell salvage autotransfusion (Group A) or allogenic transfusion (Group B). The cost of blood transfusion in Group A was (€995 ± €447) per pt & (€1220 ± €269) in Group B ($p < 0.05$).	The use of cell salvage autotransfusion results in less blood transfusion in elective lumbar fusions.
Reitman et al., 2004	IV	Retrospective cohort study of 102 pts who underwent lumbar fusion w/ either cell salvage autotransfusion or w/out autotransfusion (control). 36% of pts in the cell salvage group received additional allogenic transfusion compared to 50% of pts in control. Average blood-related cost was \$512 for cell salvage compared to \$270 in control.	Although cell salvage does decrease postoperative transfusions, it is more costly.
Carreon et al., 2009	IV	102 pts >60 yrs old requiring PLF were randomized to receive either rhBMP-2 or ICBG. Outcomes & costs were assessed at 2 yrs. SF-6D was used for utility measurements. Follow-up was 96%. No sensitivity analysis. The cost of fusion using rhBMP-2 was \$39,967. Fusion w/ ICBG cost \$42,286. In the ICBG group, there were 5 revision surgeries; in the rhBMP-2 cohort, 1 revision surgery. The 2 cohorts had similar improvement in SF-6D scores.	The cost of using rhBMP-2 is comparable to the cost of autograft for lumbar fusion surgery pts.
Glassman et al., 2008	IV	106 pts >60 yrs old randomized to either rhBMP-2 vs ICBG for anterior 1-level lumbar spine fusion. Outcomes & costs were assessed at 2 yrs. Total cost of care over 2 yrs was not significantly different (\$42,574 for ICBG & \$40,131 for rhBMP-2).	Use of rhBMP-2 is as effective as ICBG for lumbar spinal fusion w/ similar costs.
Alt et al., 2009	IV	Using pooled clinical data from previous study of 679 pts receiving either rhBMP-2 or autogenous bone graft for 1-level interbody lumbar fusion, the financial impact of rhBMP-2 was calculated from a societal perspective for 3 countries: Germany, France, & UK. Using a societal perspective (return-to-work, secondary treatments costs, & reduced surgical time) rhBMP-2 used in ALIF surgery might reduce societal costs by €8483 in Germany, €9191 in France, & €8783 in UK.	The use of rhBMP-2 is associated w/ a reduction in return-to-work time & therefore appears to increase productivity from a societal perspective.

(continued)

TABLE 1: Economic outcome: summary of evidence* (continued)

Authors & Year	Level of Evidence	Description of Study	Conclusions
Cahill et al., 2009	IV	Retrospective cohort study of 328,468 pts from NIS who underwent spinal fusion, to determine complications & charges associated w/ use of rh-BMP. For lumbar fusion cases, LOS was 3.17% increased & total hospital charges were 31.30% greater following utilization of rh-BMP (\$74,254 vs \$57,393).	Rh-BMP is associated w/ increased LOS & total hospital charges in all categories of spinal fusion.
Adogwa et al., 2011	IV	45 pts who underwent a lumbar TLIF for spondylolisthesis (single-institution registry) were retrospectively reviewed. Lumbar TLIF was associated w/ a mean 2-yr cost of \$42,854/QALY. No control group. No sensitivity analysis.	Preliminary economic data suggests lumbar TLIF might be cost-effective (<\$50,000/QALY) at a 2-yr time horizon.
Wang et al., 2010	IV	Retrospective study of 74 pts treated w/ either minimally invasive or open TLIF lumbar procedures. Mean hospital charges for open surgery were higher than for minimally invasive TLIF. For 1-level fusion: MIS, \$70,159 vs open TLIF, \$78,444.	Open lumbar TLIF is associated w/ higher hospital charges than minimally invasive TLIF.
Wang et al., 2012	IV	Retrospective cohort study of 6106 pts from NIS who underwent MIS vs open TLIF. Hospital costs were calculated w/ CCRs. Single-level MIS & open TLIF were associated w/ comparable hospital costs. For 2-level TLIF: MIS (\$33,879) was less costly than open surgery (\$35,984).	Single-level minimally invasive TLIF & open TLIF have comparable hospital costs. For 2-level TLIF, MIS might be less costly than open surgery.

* ALIF = anterior lumbar interbody fusion; CCR = cost-to-charge ratio; FRA = femoral ring allograft; ICBG = iliac crest bone graft; LBP = low-back pain; LOS = length of stay; MIS = minimally invasive surgery; NIS = Nationwide Inpatient Sample; ODI = Oswestry Disability Index; PLF = posterolateral lumbar fusion; pt = patient; QALY = quality-adjusted life year; rhBMP-2 = recombinant human bone morphogenetic protein-2; SEK = Swedish kronor; SF-6D = Short-Form 6D; SPORT = Spine Patient Outcomes Research Trial; TC = titanium cages; TLIF = transforaminal lumbar interbody fusion; UK = United Kingdom; VAS = visual analog scale.

Oswestry Disability Index (ODI) and visual analog scale (VAS) for 2 years. Patients who underwent surgery had 1 of 3 procedures: noninstrumented posterolateral fusion, instrumented posterolateral fusion, or a posterolateral circumferential fusion with pedicle screws and interbody grafts. Both direct and indirect costs were collected for each treatment group. The mean cost per patient was significantly higher in the surgical group (cost in Swedish kronor [SEK]: SEK 123,000 [US\$18,731]) compared with the nonoperative group (SEK 65,200 [US\$9929]). A significantly greater percentage of patients in the surgically treated group returned to part-time or full-time work compared with the nonoperative group (33% vs 16%, $p = 0.015$). Overall, lumbar fusion was associated with significantly greater improvements in pain and function compared with nonoperative treatment at 2 years. However, there was no difference in clinical outcome between the 3 fusion techniques studied. Compared with noninstrumented posterolateral fusion, the placement of pedicle screws increased hospital costs by 66% and a circumferential fusion procedure increased them by 103%. This study, however, did not measure QALYs, and therefore, it is difficult to interpret and generalize the data against more meaningful cost analyses.²⁶ Another significant limitation of this study is that the retrospective nature of the cost analysis, introducing the potential for significant recall bias regarding the patient's recollection of outpatient health resource utilization. Due to these design limitations, no definite conclusions regarding cost-effectiveness can be formulated from this economic analysis. It provides Level III evidence that outcomes are improved with fusion surgery for low-back pain compared with nonoperative treatment (see Table 1).

Lumbar Disc Arthroplasty Versus Posterior Lumbar Fusion

Fritzell's group performed a randomized controlled trial comparing the cost-effectiveness of total lumbar disc replacement (TDR) versus posterolateral fusion with or without interbody fusion.¹⁸ One hundred fifty-two patients with chronic low-back pain were randomized to receive either TDR (80 patients) or fusion (72 patients). QALY outcomes were assessed using EQ-5D over a 2-year time period. Direct and indirect health costs were collected. Utilization of all outpatient resources and loss of work productivity were included to calculate health costs from a societal perspective. Multi-way sensitivity analyses were performed on excluding reoperations in both groups, costs for inpatient rehabilitation, and health cost discounting (see Table 1).

Follow-up data were available on 99% of cases at 2 years. From a societal perspective the mean health cost for TDR was SEK 599,560 (US\$90,162) and for lumbar fusion was SEK 685,919 (US\$103,149). This difference in cost was not statistically significant. At 2 years after surgery both groups demonstrated an improvement of 0.4 QALYs. The study's authors concluded that lumbar TDR and lumbar fusion have similar cost-effectiveness profiles in Sweden, although TDR was associated with lower costs from a health care perspective because of a lower reoperation rate at 2 years (see Table 1).

Part 3: Assessment of economic outcome

Circumferential Lumbar Fusion Versus Posterolateral Lumbar Fusion

Soegaard et al. randomized 146 patients with chronic low-back and leg pain to either posterolateral or circumferentially instrumented fusion and followed outcomes for 4–8 years after surgery.³⁶ Outcomes were measured with EQ-5D, SF-36, ODI, and pain scores. Service utilization (i.e., surgery, reoperations, rehospitalizations, general practitioner visits, etc.) was recorded per patient by the National Patient Registry in Denmark. Service utilization is valued by national average unit costs through the DRG system of coding. A micro-costing analysis was performed, including patient costs, medications, and productivity costs. The circumferentially treated group demonstrated better functional outcome ($p = 0.004$), higher fusion rate ($p < 0.04$), and fewer reoperations (15% versus 38%) compared with the posterolateral cohort. From a societal perspective, the circumferentially treated group demonstrated significantly lower costs compared with the posterolateral group ($p = 0.012$), primarily due to the higher reoperation rate and lower return to work rate observed in the posterolateral group. This study showed an incremental savings of \$49,306 per QALY following a circumferential fusion compared with a posterolateral fusion. The study benefited from the long follow-up interval, large number of patients enrolled, and the comprehensive National Patient Registry. However, there are limitations, which include the heterogeneous population of patients with respect to presenting diagnosis and history of previous spine surgery. For example, patients with isthmic spondylolisthesis may have more favorable outcomes following lumbar fusion than other patients undergoing a lumbar fusion for different reasons. This study provides Level I evidence that circumferential fusion through a posterolateral approach is more cost-effective than stand-alone posterolateral fusion for up to 8 years following surgery (see Table 1).

Minimally Invasive Versus Open TLIF

Two retrospective studies by Wang et al. have addressed the cost-effectiveness of minimally invasive versus open TLIF.^{43,44} In a retrospective review of 59 single-level TLIF cases at one institution using hospital charges as a surrogate for hospitalization costs, Wang and colleagues found that minimally invasive single-level TLIF was associated with lower hospital charges (\$70,159) compared with open single-level TLIF (\$78,444) ($p = 0.027$). Using the Nationwide Inpatient Sample (6106 cases) and applying CCRs to estimate hospital costs, Wang et al. found that minimally invasive single-level fusion was associated with hospital costs similar to those for open TLIF; however, for 2-level procedures, hospital costs of minimally invasive TLIF procedures (\$33,879) were lower than costs of open surgery (\$35,984; $p = 0.0023$). Neither study included outcome measures, so ICERs could not be calculated to assess cost-effectiveness (see Table 1).

A recent preliminary study reported cost-effectiveness data for TLIF using EQ-5D to measure QALYs gained over a 2-year time period. Adogwa et al. calculated health costs from a societal perspective by includ-

ing inpatient and outpatient Medicare costs as well as workday losses.¹ While this type of analysis was limited because there was no comparison group, the results demonstrated that TLIF might be cost-effective (\$42,854/QALY). Comparative studies are needed to calculate ICERs to validate these findings (see Table 1).

Type of Interbody Device Used for Lumbar Interbody Fusion

Freeman et al. randomized 83 patients with chronic low-back pain undergoing circumferential fusion to receive either a titanium cage (TC) or femoral ring allograft (FRA) in an effort to determine which interbody graft was more cost-effective.¹⁶ Outcomes were measured by ODI and SF-6D at various intervals for up to 2 years following surgery. Direct cost data were derived from the National Health Service, using local center-specific unit costs for individual health resources. The indirect costs were measured by the human capital approach, which is based on the total expected production losses for an individual worker for the duration of disability.²² The cost of TC was approximately 10 times higher than FRA (£1609.76 [US\$2583] vs £158.92 [US\$255]), and the mean total cost per patient was significantly higher in the TC group, £9052 (US\$14,531) compared with £7102 (US\$11,399) ($p < 0.001$). In addition, the mean QALY gained per patient over 24 months was significantly greater in the FRA group (0.1914) compared with the TC group (0.0522). Because the FRA proved to be less expensive and increased QALYs compared with a TC, an ICER was not necessary. Finally, using the human capital approach to cost productivity, total gross mean earnings in the 2 postoperative years were £7456 (US\$11,968) in the TC group and £14,517 (US\$23,303) in the FRA group. A higher percentage of FRA patients had a positive change in employment status following surgery compared with TC patients (21.6% vs 9.8%), and FRA patients were more likely to see an improvement in their salary after surgery. The strength of this study lies in its randomized design, excellent outcomes data, and comprehensive cost analysis. However, some utility data were missing, requiring estimation in the analysis. In addition, a few important health care resources were omitted from the cost analysis, including radiology costs, medication, outpatient services, and primary care costs. The clinical observations of Freeman et al. are supported by an earlier randomized trial by McKenna et al. that found improved clinical outcomes in patients implanted with FRA compared with TC.²⁷ These authors speculated that the improved pain relief with FRA may be due to the more physiological transfer of loads as the fusion matures compared with point loading with titanium cages. Overall, the study of Freeman et al. provides Level II evidence that the use of femoral ring allograft for lumbar interbody fusion is more cost-effective than the use of a specific titanium cage when performing a posterolateral circumferential fusion (see Table 1).

Cost-Effectiveness of rhBMP

Cahill et al. reviewed a retrospective cohort of 328,468 patients undergoing lumbar fusion procedures

from 2002 to 2006, selected from the Nationwide Inpatient Sample database, in an effort to determine the cost associated with the application of recombinant human bone morphogenetic protein (rhBMP) as a fusion enhancer.⁷ The usage of rhBMP has increased from 0.69% of all fusions in 2002 to 24.89% of all fusions in 2006. The primary outcome measures included the rate of rhBMP utilization, complications, length of stay, and associated hospital charges. There were no differences in the rates of overall complications based on the application of rhBMP. The use of rhBMP was associated with an extended hospitalization (3.17% increase). The utilization of rhBMP was associated with a 20% increase in total hospital charges compared with those undergoing fusion without rhBMP (\$74,254 vs \$57,393). This analysis, however, is limited by the lack of clinical outcome data, and since only total hospital charges were considered, with a wide range in charges identified between different institutions, \$54,737–\$102,663 for lumbar fusions supplemented with rhBMP and \$39,660–\$83,608 when rhBMP was not included. This study provides Level IV evidence that rhBMP is associated with increased length of hospital stay (LOS) and total hospital charges in all categories of spinal fusion (see Table 1).

Glassman et al. conducted a randomized trial of rhBMP-2 versus iliac crest bone graft (ICBG) in patients over 60 years of age undergoing either single-level or multilevel instrumented posterolateral lumbar fusion.²⁰ Outcomes were measured up to 2 years after surgery utilizing validated outcomes instruments, including the ODI, SF-36, and numerical pain scales. Direct costs were obtained from actual reimbursement to the hospital. Where actual payments could not be determined, a Medicare fee schedule was used to assign direct cost. No significant differences in any of the outcome measures were identified between the 2 treatment groups. However, the fusion rate at 2 years, as measured by CT and presence of bridging bone, was significantly higher in the rhBMP-2 group (86.3% vs 70.8%, $p = 0.030$). Including revision surgery and outpatient costs (i.e., postoperative rehabilitation), the total cost of care over 2 years was not significantly different for 2 groups (\$42,574 for the ICBG group vs \$40,131 for the rhBMP-2 group). This study provides Level IV evidence that either ICBG or rhBMP-2 may be considered as posterolateral fusion graft options in patients over the age of 60 (see Table 1).

Using the same data as Glassman et al., Carreon et al. performed a cost-utility analysis of rhBMP-2 versus ICBG.⁸ Utility was estimated from the SF-6D.⁴ As described above, costs were determined from actual reimbursement to hospitals and physicians participating in the trial and included reimbursement for inpatient and outpatient services, radiographic imaging, and medications. There was no significant difference in change in utility between the 2 groups at any time point. The total cost of using rhBMP-2 was \$39,967, with a 0.11 mean improvement in SF-6D; for ICBG, the cost was \$42,286, with a mean improvement of 0.10 in SF-6D. The authors failed to account for indirect costs such as lost wages or out-of-pocket expenses. This study provides Level IV evidence that the cost of using rhBMP-2 is comparable to the cost

of autograft for patients undergoing lumbar fusion surgery (see Table 1).

Alt et al. performed a cost analysis on a previously studied cohort of patients who either received rhBMP-2 or ICBG during lumbar fusion.^{2,6} The study population included 279 patients randomized to either rhBMP-2 or ICBG and 400 patients from a prospective nonrandomized cohort. The original trial demonstrated significant reduction in surgery time (reduction of 54 minutes) and blood loss (reduction of 66 ml) when rhBMP-2 was used instead of ICBG. Patients in the rhBMP-2 group required fewer revision operations and returned to work earlier. Finally, the fusion rate and clinical outcomes of patients in the rhBMP-2 group were significantly better than those in the ICBG group. The authors performed a retrospective cost analysis from data collected in 3 countries: Germany, France, and the United Kingdom (UK). Direct costs were estimated from the expense associated with the use of rhBMP-2, operating room time, and revision surgery. Indirect costs were estimated from the loss of productivity and the national average of gross wages. From a societal perspective, the overall savings associated with use of rhBMP-2 compared with ICBG for Germany, France, and the UK were €8483 (US\$11,745), €9191 (US\$12,726), and €8783 (US\$12,161), respectively. This study is limited by the retrospective study design and failure to account for costs associated with out-of-pocket expenses, medications, or outpatient treatment. This study provides Level IV evidence that the use of rhBMP-2 is associated with a reduction in return-to-work time and may increase productivity from a societal perspective.

Conflicting Data Regarding the Cost-Effectiveness of Cell-Salvage Autotransfusion

Savvidou et al. randomized 50 patients undergoing instrumented lumbar fusion to a group that received cell-salvage autotransfusion and a group that did not.³⁴ The total amount of allogeneic and cell-salvage blood used per patient was recorded. The cost for each unit of allogeneic blood (€450 [US\$623]) versus cell-salvage blood (€370 [US\$512]) was determined from the Greek ministry of health. The total transfusion cost in the group that received cell-salvage autotransfusion was significantly lower than the group that did not (€995 [US\$1377] versus €1220 [US\$1689], $p < 0.05$). Because this study did not measure outcomes, it is impossible to perform an adequate cost-effectiveness analysis regarding the use of autotransfusion. This study provides Level IV evidence that the use of cell-salvage autotransfusion lowered the costs of transfusing blood for elective lumbar fusions (see Table 1).

Reitman et al. performed a retrospective analysis of patients who had undergone instrumented lumbar fusion with and without cell-salvage autotransfusion.³⁰ There was no significant difference in blood loss between the 2 groups, and 38% of the blood in the study group was returned as cell-salvage autotransfusion. The average charge of the cell-salvage was \$512 per patient compared with \$270 per patient in the control group. The authors concluded that the cost of blood replacement was higher in the cell-salvage autotransfusion group. As with other studies investigating the application of cell-salvage autotransfu-

Part 3: Assessment of economic outcome

sion, there are insufficient data to perform a meaningful cost-effectiveness analysis. This study provides Level IV evidence that use of cell-salvage autotransfusion is more costly than normal postoperative transfusion (see Table 1).

Summary

Lumbar fusion for certain degenerative spine disorders can be effective in improving clinical outcomes and long-term quality of life when compared with nonoperative therapy. Comprehensive economic analyses that include long-term clinical outcomes data and both direct and indirect costs will be necessary before any recommendations can be made regarding the cost-effectiveness of various methods of lumbar fusion. Given the significant impact of lumbar degenerative disease, it is essential from a societal perspective that these studies be conducted. Recent cost-analyses have demonstrated the long-term benefits of circumferential fusions over posterolateral fusions, FRA over TC when performing an interbody fusion, and that both rhBMP-2 and ICBG are associated with similar costs.

Key Issues for Future Investigation

As new technologies for lumbar fusion are introduced and studies are performed to assess their effectiveness, the inclusion of an economic analysis is essential. Appropriate long-term follow-up is important when designing trials, as the benefits of lumbar fusion, both clinically and economically, may be apparent several years following the operation. The major challenge for investigators is to determine the most reliable estimate of cost. Medicare reimbursement may underestimate real costs, and medical charges may grossly overestimate true costs. New methodology is needed to allow for meaningful long-term assessment of health cost, and it may be that the best “laboratory” for these studies is a well-run health care system that follows costs directly along with patient outcomes as a matter of course.

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